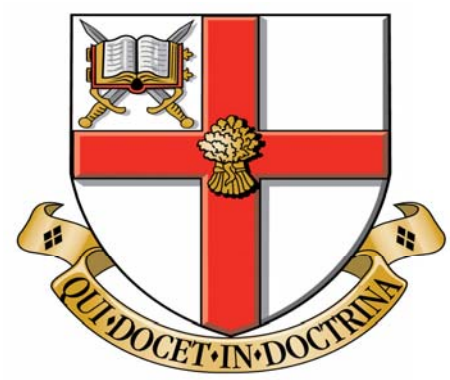

KNOWING AND COMPLYING: PATIENT AWARENESS OF ASPIRIN USE FOR SECONDARY PREVENTION OF STROKE AND TRANSIENT ISCHAEMIC ATTACK.

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ABSTRACT

KNOWING AND COMPLYING: PATIENT AWARENESS OF ASPIRIN USE FOR SECONDARY PREVENTION OF STROKE AND TRANSIENT ISCHAEMIC ATTACK.

The aim of this study was to gain understanding into compliance behaviour with aspirin as prescribed for secondary prevention of stroke. The study used a convenience sample of 20 patients who had been admitted to a NHS Trust following a subsequent stroke or transient ischaemic attack. Semi-structured interviews were used to explore the use of aspirin at the time of admission. Patient perception of personal risk and risk factors for stroke were explored. Where appropriate, responses were checked against health care records for comparison. The findings suggested that the majority of patients were compliant with aspirin, however deficiencies in current practice were identified. Patients lacked awareness of their risk factors and their risk of having a further stroke. They were also unaware why they were taking aspirin. Strategies that assisted compliance behaviour and reasons for non-compliance were identified.

Key words: compliance, non-compliance, risk perception, stroke.

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DECLARATION

This work is original and has not been submitted previously in support of any qualification or course.

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Chapter 1

INTRODUCTION

1.1 INTRODUCTION

Health promotion encompasses the fields of health education, public policy, community action and environmentalism. It plays a pivotal role within the prevention of disease, the maintenance of health and raising individual and public awareness of the wider issues connected with health (Naidoo and Wills, 2000). Compliance is becoming an increasingly important aspect of health care with non-compliance of prescribed medication contributing significantly to poorer health outcomes (Jones, 2003), treatment failures (Myers and Midence, 1998) and major challenges for health professionals.

Stroke is predominantly a preventable disease. It is the third most common cause of death and adult disability in the UK and the Western world (Wolfe, 2000). The significance of this burden, which is likely to continue to rise due to demographic changes, is now recognised. Stroke was identified and prioritised by the government in 1992 (DOH) and 1998 (DOH) as an illness that demanded a reduction in incidence and mortality. Effective stroke prevention strategies have consequently been designated a national and international priority (DOH, 1998; Aboderin and Venables, 1996).

The potential for improvement in primary prevention of stroke is well researched but there is limited evidence on the state of secondary prevention (Hillen et al. 1999).

However the efficacy of secondary stroke prevention strategies through treatment of major risk factors are increasingly recognised (Sappock et al. 2001).

Within the medical literature the protective role of aspirin in secondary prevention for stroke is well researched and recommended (Antiplatelet Trialists Collaboration, 1994). Audits and databases provide evidence that aspirin is now increasingly prescribed as secondary prevention for appropriate patients. Aspirin is required to be taken indefinitely, however it remains unclear how compliant patients are as there is a lack of research in this area. If patients do not comply the moderate protective affects of aspirin are consequently reduced. An exploration of compliance behaviour is beneficial as it has implications for resources, health, health promotion and patient education. A glossary is provided in the appendices.

1.2 LOCAL BACKGROUND AND JUSTIFICATION FOR THE STUDY

A Stroke Register has been maintained for the last seven years by the Stroke Co-ordinators within the Trust. The register is electronic and linked to the hospital's electronic patient information system. All patients with a diagnosis of stroke or transient ischaemic attack (TIA), who present to the hospital are identified and included onto the register. The numbers of patients during this time has consistently risen with 2002-2003 witnessing 1,193 acute stroke /TIA presentations.
(See table 1.1)

Table 1.1 Stroke/TIA Episodes at a NHS Trust 1999-2003

Year	1999 - 2000	2000 -2001	2002 -2003
Total number of stroke/ TIA's	793	906	1193
Previous stroke	21%	15%	28%
Previous TIA	29%	26%	25%

Data from the Stroke register 2001 - 2002, indicates 18% of patients admitted with a recurrent stroke and 32% of patients admitted with a previous TIA had not been prescribed antiplatelet or anticoagulation medication. During 2002-2003, the register identified 28% of acute stroke and 25% of TIA admissions had either had a previous stroke or TIA. 34% of these patients were not documented as having been prescribed antiplatelet or anticoagulation therapy. However the register does have limitations, it does not distinguish patients for whom aspirin is contraindicated or provide any information regarding compliance with prescribed aspirin therapy.

For secondary stroke prevention it is essential to ascertain if patients are compliant, and also to gain an insight into factors that aid or inhibit compliance behaviour. Whilst the database provides quantitative data it fails to provide any qualitative data to assist in the understanding and exploration of these issues. The patients included in this study have previously suffered a stroke or a TIA, prior to being admitted into hospital with a further event. If current management guidelines are adhered to all appropriate patients should be prescribed and taking aspirin on admission. Prescriptions can be monitored by the database. But is aspirin taken regularly? Are patients aware of why it is prescribed and of their risk of a further event?

Recent government health papers (DOH, 1992, 1998, 2000) promote patient involvement in all aspects of their health care including decisions about medication. This study is therefore timely. Evidence based guidelines affirming the use of aspirin and targets to reduce the incidence of stroke are only useful and achievable if patient perceptions and views are considered and understood. A prescription for aspirin does not confirm that patients are actually taking it. An exploration of compliance from the patients' perspective and factors that may effect long term compliance positively and negatively in a population at high risk of stroke will add to current knowledge and aid health promotion strategies and developments for secondary stroke prevention.

1.2.1 The Research Questions

The research questions the study will address are: -

- Do patients recall being prescribed aspirin for secondary prevention of stroke/TIA?
- How compliant are patients with their aspirin therapy?
- What factors facilitate compliance?
- What factors inhibit compliance?
- Are patients aware of their risk factors for stroke?
- At this exploratory level is there a relationship between compliance and other demographic factors? (age, gender, social characteristics)

1.3 OVERVIEW OF THE STUDY

The study is presented in five chapters. The introduction has described the rationale behind the study and introduced the research questions. Evidence of the plethora of

issues connected with compliance and how medical perceptions have changed over time is provided in the literature review. It also highlights the lack of research that has been carried out in this area and sets the study within context. The methods chapter discusses the relationship between the study's research questions and the methods used to explore them. The results are presented succinctly and then explored and interpreted in relation to the research questions within the discussion chapter. Implications for health workers and recommendations to further research within this area are suggested.

Chapter 2

LITERATURE REVIEW

2.1 INTRODUCTION

This chapter explores and identifies issues that have implications for health promotion and health education related to compliance. Compliance is recognised as being critically important and a major problem within health care. Health promotion is underpinned by principles of empowerment, equity, participation and collaboration (Naidoo and Wills, 2000). All of these values are integral to compliance if it is supported in a health promoting way.

The focus of the study is on compliance for secondary prevention of stroke with aspirin therapy, for which there is a paucity of research. Within this literature review the few studies identified are reviewed and critiqued. Compliance is an extremely complex issue and decisions related to compliance are based on individual experiences, values and perceptions. The investigation and analysis of the literature will facilitate discussion of these factors and provide an understanding of the processes involved with compliance that are pertinent to health behaviour. The salient themes discussed within this literature review being compliance, risk and patient perceptions.

2.1.1 Searching Strategy

A literature search was conducted using the 2004 versions of the computerised databases, PROQUEST, CINHAL, and MEDLINE. English language literature

published between January 1980 and February 2005 was searched using the following key words: stroke, secondary prevention, aspirin, compliance, adherence and concordance. A process of cross referencing articles was also undertaken.

2.2 THE EFFICACY OF ASPIRIN

An aim of this study is to establish if patients are compliant with aspirin, it is therefore appropriate to review the evidence to support its efficacy. Aspirin is one of the most commonly used drugs of all time, being widely used for its anti-inflammatory, analgesic and antipyretic properties. Within stroke management it is used for its protective antiplatelet action which was not recognised until the 1970's (Hart and Harrison, 1966). Since then evidence based guidelines have been published which propose and endorse the use of aspirin for secondary prevention of stroke (DOH, 2001; RCP, 2000; RCP, 2004). Patients who have suffered an ischaemic stroke or TIA are at high risk of a further event. Taking aspirin reduces this risk by approximately 23% as well as reducing the risk of myocardial infarction and vascular death. This effect is the equivalent of avoiding 37 serious further events per 1,000 people treated (Warlow et al. 2001).

The efficacy of aspirin for prevention of subsequent stroke, is equally evident regardless of sex and age, in patients who are hypertensive or normotensive and those with diabetes mellitus (Antiplatelet Trialists' Collaboration, 1994). The cost of aspirin is minimal and only a low dose of 75mg once a day is required. It is a drug that is reasonably well tolerated at this low dose, however there are risks associated with taking long term aspirin. They include a slight risk of intracranial bleeding, (1-2 per

1,000 people) and a small risk of gastrointestinal bleeding. However, Gubitz and Sandercock (2000) claim the benefits for high-risk patients outweigh the risks.

2.3 THE CONCEPT OF COMPLIANCE

To understand health behaviour in relation to taking medication it is necessary to establish what is understood by the term "compliance". The concept of compliance is continually debated within health literature. According to Kyngas and Lahdenpera (1999) and Gray et al. (2002) compliance has no generally accepted definition. The term originated from the military (Falk, 2001, cited by Scherman and Lowhagen, 2004) and definitions generally imply to "follow a regimen". Definitions of compliance are authoritarian and can be coercive or judgmental (Scherman and Lowhagen 2004). Sackett and Haynes, (1976, p.2) provide an example of an authoritarian and coercive definition, "... the extent to which patients' behaviour coincides with the clinical prescription, regardless of how the latter is generated." Less than a decade ago Corlett (1996, cited by Bonner, 2002, p. 33) presented a further authoritarian definition "... the extent to which a person's behaviour (in terms of taking medication, following diets, or executing lifestyle changes) coincides with medical advice."

Both definitions promote the health professional as "the expert" who is in a position of power, and the patient as powerless. Patients however are understood to construct their own interpretation of compliance, which may be divergent from the health professionals. Feuerstein et al. (1988, p.52, cited by Lannon, 1997) provides an example of a patients' definition where the power relationship is reversed with the

patient in the position of power, "... the willingness of the doctor to undertake diagnostic and therapeutic measures in co-operation with the patient."

2.3.1 Non compliance - the "Patients' Problem"

Many explanations for non-compliant behaviour are presented within the literature. Previously it has primarily been interpreted as being the "patient's problem". This implies a decision has been made not to follow medical advice: the only rational activity recognised by health professionals being compliant behaviour. Non-compliant behaviour has been labelled as problematic, as it "...contravenes professional beliefs, norms and expectations regarding the 'proper' roles of patients and professionals" (Playle and Keeley, 1998, p.304). Such patients have been stereotyped as irrational, suffering from defects, (Perkins and Repper, 1999) deviant, (Playle and Keeley 1998) or suffering from a lack of knowledge or understanding (Russell et al. 2003). More recently the focus of non-compliant behaviour has altered. It now encompasses wider social and environmental perspectives, moving away from judgements that "the patient is the problem".

2.3.2 Changing Perceptions by Health Care Professionals

Currently amongst health care professionals there is a wider understanding and appreciation of what constitutes non-compliant behaviour. Compliance is now understood to encompass more than an act of behaviour by the patient that coincides with medical advice. This is reflected by the introduction of different terminology, which is often used interchangeably within the health literature to replace "compliance". The expressions used include the terms adherence and concordance which convey statements of fact rather than individual blame (McDonald et al. 2002).

Therefore they communicate a less paternalistic and judgmental action and place greater emphasis on patient involvement in decision making. Leventhal (1992) highlights they stress the self-regulatory activity of the patient and Barber (2002) comments they remove stigma and encourage patients to be open about their medication use, therefore they encourage safer practice. Changing terminology has helped to divorce the previous authoritarian definitions and judgmental views from current thinking and practice.

2.3.3 Synonyms for Compliance

Within the literature adherence is often used as a synonym for compliance (Sawyer and Aroni 2003). This term was introduced into healthcare as it was less value laden than compliance (Barber 2002). However definitions convey differing understandings, Buchmann (1997) describes adherence as including the action of sticking to, supporting or following an idea. The World Health Organisation's (WHO, 2003, p.7) definition is "The extent to which the patient follows medical instructions." This definition is similar to those of compliance, which emphasise the power of medicine and dominance of the professional over the passive patient. Consequently the term adherence may be seen as a euphemism for compliance.

WHO (2003) stress that there is a need to differentiate between the two terms, and claim that adherence implies patient agreement to any recommendations. With respect to long term adherence, WHO (2003, p.3) have adopted the following definition "The extent to which a person's behaviour - taking medication ... corresponds with agreed recommendations from a health care provider." This views the patient as an active participant, in agreement with the health professional and not a

passive recipient of expert advice. The literature reports changes in both the health professionals' and patients' behaviour with the use of the term adherence (Sawyer and Aroni, 2003). However, Barber (2002) comments that although the term adherence is used widely by researchers and reported within the literature it has had limited use clinically and the use of the term compliance seems to be popular again.

The other term used within the literature with respect to compliance is "concordance." This is viewed as a more inclusive concept that implies shared decision making between the patient and professional health care worker (Elwyn et al. 2003). For concordance to be achieved it is essential patients have access to accurate, relevant and understandable information. Furthermore there has to be an acceptance and respect of the patients' rights to make decisions or choices that may conflict with guidelines and the health professionals' advice. Potential problems within clinical practice are identified by Jones (2003), who expresses concern that concordance should not be seen as a gift-wrapped version of compliance and Heath (2003) is apprehensive that coercion may exist within concordant relationships but be concealed.

2.3.4 The Changing Meaning of Compliance

The use of the differing language has also caused confusion within health care. Jones (2003) claims that many professionals do not understand "concordance" or have not heard of the term. Boyle and Chambers (2000) believe the use of "adherence" and "concordance" are too technical and confusing whilst the word "compliance" is more straightforward. There are suggestions in the literature that the concept of compliance has been reformulated. Kyng et al. (2000, p.677 cited by Lahdenpera, 2003) illustrates

this with a definition of compliance that is similar to adherence "...an active, intentional and responsible process whereby patients work to maintain their health in collaboration with the health care professionals." Implying patients actively participate in their health care and have associated responsibilities.

2.3.5 Changing Relationships

Acknowledgement is made in the literature that relationships and communication patterns between health professionals and patients are becoming more interactive and a two way process. Health professionals are now increasingly encouraged to recognise patients as experts of their own health (DOH, 2003a). The Royal Pharmaceutical Society (1997) advocates that a therapeutic alliance should be achieved between the health professional and the patient, based on respect of patients' beliefs and wishes. In such a relationship, discussion and negotiations should occur which lead to patient informed choice and agreement. This relationship may be affected by the pressures on health professionals and the organisation, brought about by the National Service Frameworks and the financial benefits of the new GP contract (Lewis et al. 2003). The impact of which may limit patient preferences in order to achieve targets. It could be argued that interventions to increase compliance are incompatible with patient choice.

2.4 STUDIES OF COMPLIANCE

It is understood that between one third and one half of patients intentionally or unintentionally do not take their prescribed medication as directed (Barber 2002).

Non compliance compromises the effective management of illness and disease and is identified as a major cause of readmission to hospital (Berry, 2004). Non-compliance also raises concerns regarding the effective use of resources and has implications in the assessment of efficacy of treatments. It is therefore pertinent that compared to the large number of research trials for new treatments there are far fewer rigorous trials that investigate compliance (Mcdonald et al. 2002). Comparably there are also few studies that relate compliance issues to health and patient outcomes (Murray et al. 2004).

2.4.1 Compliance with Aspirin Therapy

There are studies, which have investigated secondary stroke prevention from the perspective of compliance. They include compliance with antihypertensive, diabetic, and cholesterol lowering therapies and changes to a healthier lifestyle. These studies have been primarily carried out to identify issues and develop interventions to enhance compliance. However there have been very few studies investigating compliance with aspirin therapy.

Sappok et al. (2001) conducted a study of compliance, recruiting stroke patients on discharge after a stroke and compared the compliance of various antithrombotic agents including aspirin one year later. The results revealed high adherence rates at one year with all the agents (87.6%). However this study could be potentially biased towards adherence as patients were recruited into the study on commencing medication. The Hawthorn effect may explain the high compliance rates, as the patients knew they would be followed up at one year. Moreover, the patients had all been managed on a stroke unit rather than general wards, where the staff have been shown to be more

committed and knowledgeable about stroke care and management (Langhorne and Dennis, 1998).

Another study was identified by Hillen, et al. (1999), which investigated the use of antiplatelet therapy after a first stroke. This study only examined compliance behaviour at three months after stroke using data from a stroke register. Compliance of aspirin was found to be high in those patients who where prescribed the drug. However 24% of eligible patients were not prescribed antiplatelet therapy. It is acknowledged within the study that patients may have commenced antiplatelet therapy after their stroke, but discontinued due to complications by the three-month data collection point. The method of data collection did not allow for this information to be gathered. Data were collected very early following the stroke and results may have been biased due to the closeness of the event. These studies reported either compliant or non-compliant behaviour. No understanding of the degrees of non-compliance or reasons for patients' decisions were given. As secondary prevention is required indefinitely both studies would have been more informative if a longitudinal approach had been used to monitor compliance.

In some of the studies reviewed there is a lack of definition and clarification over the terminology. "Compliance" and "adherence" are used separately in some articles but interchangeably in others. It is uncertain when "adherence" is used, if it implies patients have previously agreed to take the medication, therefore excluding patients who had not agreed to take medication and so biasing the study.

2.4.2 Prescribed Aspirin

This literature review is primarily concerned with the compliance of aspirin however for patients to be compliant, aspirin needs to be offered and prescribed. In primary care within the West Midlands, Short et al. (2003) uncovered sub-optimal aspirin prescribing for secondary prevention of stroke. Patient resistance was a cause identified which included patients 'hanging on' to medical advice received prior to the 1970's. Short et al. (2003) explains this behaviour as being "haunted by the ghosts of doctors past." Reluctance to take aspirin was also evident in patients who had previously suffered side effects with aspirin or had heard of other people who had bad experiences. Clinical uncertainty by the health professional about the risks and benefits to certain patients was also identified as a reason for not prescribing.

The culture within the NHS has changed, becoming less paternalistic and encouraging active patient participation. Less value-laden terminology has been introduced to replace "compliance", however "compliance" remains the favoured term. Moreover it has received an updated definition that reflects current clinical practice. Have these changes affected compliance behaviour? Factors that have an impact on compliance behaviour will now be discussed.

2.5 COMPLIANCE BEHAVIOUR

Gaining an understanding of why individuals decide to take or not to take their medication can help with planning health strategies. The determinants of non-compliant behaviour are complex and poorly understood (McDonald et al. 2002). Over 200 factors have been identified as attributable (Hayes, 2001, cited by Barber,

2002). Reasons appear to be multi-factorial including psychosocial, demographic and medical related characteristics. No consistent relationship however has been found that links patient characteristics with poor medication compliance.

There is a need to assess if patients are intentionally or unintentionally non-compliant as individuals can have many reasons for not taking their medication. Consequently non-compliance can be viewed as a rational act rather than an act of disobedience. Patients are more likely to make a rational decision not to comply if they have experienced an undesired outcome or if consequences of complying outweigh any perceived benefits. Lack of perceived benefits are identified as a significant factor for non-compliance (Murray et al. 2004), implying if patients perceive a benefit, they will comply with treatment (Kaplan and Simon, 1990).

Kyngas and Lahdenpera (1999) divide the determinants of non-compliance into internal and external factors, with the former referring to patient characteristics and the latter encompassing all other determinants. Murray et al. (2004), Dantas et al. (2004) and WHO (2003) identify the interplay of four major factors involved in compliance: patient related factors, health care team and systems related factors, condition related factors and characteristics of therapies. Related issues around each factor will be explored.

2.5.1 Patient Related Factors

WHO (2003, p.9) outline patient related factors as "... the resources, knowledge, attitudes, beliefs, perceptions and experiences of the patient." Traditionally patient related factors have been over emphasised as determinants of non-compliance.

Morisky et al. (1986) suggests this is because they are easier to measure. Patient related factors imply that non-compliance is the patient's fault, with the assumption being, compliance will be improved if their behaviour is changed (Oldridge, 2002).

2.5.2 Health Beliefs

Patient values, perceptions and health beliefs are major influences in determining health behaviour and compliance. Lewis et al. (2003) explains and warns that patient decisions are based on individual values, beliefs, priorities and information available to them rather than scientific facts alone. Secondary prevention strategies presume individuals wish to avoid further events or illness. It is assumed therefore that individuals will tolerate any inconvenience from taking long term medication to reduce their risk (Trewby et al. 2002).

2.5.3 Patient Perceptions

Murray et al. (2004, p.40) contends if patients are to be compliant they must perceive a need. This need is measured by individual perceptions based on an interpretation of the symptoms, severity of illness and the ability to cope with the illness. Individual perception and health behaviour can change throughout a patient's lifetime due to maturity, experiences and situations.

Lannon (1997) stresses the importance of establishing how patients feel about their diagnosis, and identifies anger about an illness as a factor that inhibits compliance. Compliance can also be negatively affected, if the perception of the illness is minor or if the illness is denied (Lannon, 1997). Denial of illness has been found in all populations, regardless of the severity of illness or amount of education given

(Cramer et al. 1989). Non-compliance in this instance is viewed as a method by which the individual seeks consonance with their former self, the one who did not require medication (Carder et al. 2003).

2.5.4 Patient Lifestyle

In studies that have explored medication compliance in relation to other risk factors for stroke, non-compliance was found to be associated with ignorance, (Seltzer et al. 1980 cited in Perkins and Repper, 1998) gender, and employment status. Shea et al. (1992) identified, in a study of compliance of antihypertensive therapy, that males were more compliant then women and the unemployed were less compliant then the employed. In study with cholesterol lowering medication by Kyngas and Lahdenpera (1999) individuals who smoked and drank alcohol were identified as being less compliant than individuals who did not smoke or imbibe. This suggests individuals who undertake more risky behaviour have a less healthy lifestyle.

Compliance patterns can change over time and the ageing process may also impact on this. Non-compliance in the elderly introduces specific factors including forgetfulness, lack of understanding about medication, lack of supervision and difficulties managing medication (Murray et al. 2004; Lumme-Sandt and Virtanen, 2002). Older adults, due to co-existing medical conditions, are often prescribed numerous medications which complicates their medication regime. Barat et al. (2004) describes a tendency for non-adherence if patients are on three or more drugs.

2.5.5 The Health Care Team and System Related Factors

Organisational and system related factors are identified as contributing to patient compliance. Barber (2002) introduces the term medical error when the reason for non-compliance lies within the organisation. Factors include: insufficient time taken to explain during consultations; being given inadequate information; being ignored or patronised and also the health providers age, gender and nationality (Kiortsis et al. 2000; Shye et al. 1990, cited by Renn et al. 2002). Patient satisfaction with health interactions was found by Smith et al. (1987) to correlate positively with compliance and has been identified as a predictor for future compliance.

Within the literature the importance of enabling patients to participate in their care is repeatedly stressed, as the way patients are treated impacts on their behaviour. (Lannon, 1997; Renn et al. 2002; Renn,2003; WHO, 2003). Lumme-Sandt and Virtanen, (2002), claim it is important for patients to feel independent and be considered as significant partners. Moreover Saounatsou et al. (2001, p.437) believe compliance is a patient responsibility, they also acknowledge that it, is "... a by product of the interaction between the patient and the health care givers."

2.5.6 Lack of Knowledge and Information

Many studies have investigated lack of knowledge and information as contributing factors for non-compliance with contradictory findings. The amount of information required has been questioned by Berry et al (1997). They established that patients often want more information about their treatment than doctors believe. Gonzalez-Fernandez et al. (1990, cited by Kyngas and Lahdenpera, 1999) claim better rates of compliance can be demonstrated in patients with increased knowledge. Barat et al.

(2004) describes in a study of 75 year olds living alone where their increased knowledge of drugs was positively associated with adherence. In other studies however, including Kiortsis et al. (2000) and Van der Pligt (1998) individual knowledge of increased risk of illness did not influence compliance with treatment or change behaviour. This was also demonstrated in a study by Barker and Naphine (1994, cited by Boyle and Chambers, 2000) who concluded that nurses who are considered to be aware of the importance of complying with medication were just as likely to be as non-compliant as the general public.

2.5.7 Characteristics of Therapies

The belief in the efficacy for a treatment has been positively associated with compliance (Kiortsis et al. 2000). The efficacy of aspirin is well researched and has been discussed earlier. Patient concerns and significant factors that negate compliance include the complexity of the treatment regimen, unpleasant side effects, that may be real or perceived, and lack of immediate benefit. Horne (1999) identified other patient anxieties with long term medication use which include becoming dependent or addicted and concerns that the drugs may become less effective over time.

Elwyn et al. (2003) identifies physical and psychological problems patients can experience when adjusting to taking long term medication. Psychologically having to take medication can be seen as a stigma, as it confirms rather than dispels the impression of illness (Scherman and Lowhagen, 2004). Physically, Lannon (1997) claims individuals need to develop a behaviour to support their daily medication regime. Compliance rates were found to increase when taking medication became

incorporated into part of a daily routine such as with a meal or at bedtime (Kiortsis et al. 2000).

2.5.8 Condition Related Factors

Characteristics of an illness, that have an effect on compliance include: symptoms of the illness; level of any disability; availability of effective treatments and individual cultural interpretation of the illness (WHO, 2003). Misconceptions held by patients also hinder compliance (Stimson, 1974, cited in Noble 1986). For example the belief that medication need only be taken when you feel ill. Conversely, Kaplan and Simon (1990) found good compliance rates in patients whose health was improving, and less compliance in patients with failing health. Likewise no consistent relationship has been found between severity of symptoms and compliance rates. Tamaroff et al. (1992) found non-compliance to be equally high for patients suffering from severe chronic pain and illnesses and those who were symptom free.

A challenge for secondary prevention is that the threat of further illness is orientated to the future. According to Coyne and Lazarus (1980, cited by Scholtz, 2000) this can be interpreted as an advantage as it provides time for the individual to reduce or reverse the threat. Equally it can be a disadvantage as the danger from the threat is not imminent which allows time for denial and avoidance strategies. There is now an awareness of the plethora of factors that may effect compliance behaviour. Health professionals must consider these factors when offering health advice. Risk perception is an important component in compliance behaviour, therefore it is essential for risk to be communicated effectively.

2.6 RISK COMMUNICATION

Risk is defined by Naidoo and Wills (2000, p.61) as "assessing the chance or probability of a disease or condition occurring." Therefore it is not certain that the illness or negative consequences will definitely occur. The way risk is communicated and presented at either a population level or an individual level has a significant effect on how the risk is perceived and interpreted (Paling, 2003). The perception and decisions around risk are not made in a context-free vacuum, but affected by social norms, cultures and lifestyles, which differ in various situations.

Effective risk communication is the basis for informed decision making and a key public health strategy (Cook and Bellis, 2000; DOH, 2000). To participate in care and make an informed decision patients require reliable individualised information. The information delivered should include risk factor identification, treatments and their risk of having a subsequent event.

Risk factors are defined as:

> "An aspect of personal behaviour or lifestyle, an environmental exposure or an inborn/inherited characteristic which on the basis of epidemiological evidence is known to be associated with health related conditions considered important to prevent." (Last, 1988).

2.6.1 Absolute and Relative Risk

The way risk is calculated can affect its impact, it can be calculated in absolute or relative terms. Last, (1988) describes absolute risk as, a calculated risk of an event in the population under study, and relative risk as the ratio of an event among the exposed compared to the risk amongst the unexposed. The use of relative risk has been found to be more persuasive and influential for compliance with treatment

(Berry, 2004), but equally responsible for causing unnecessary alarm. In order to reduce the bias caused by relative risk the absolute risk should also be given (Berry, 2004) Edwards et al. (2002) comments that it may be justified to use relative risk in order to achieve the greatest public health gain. Communicating risk in this way however may not be consistent with informed choice.

The task of communicating risk is complex and the process is not aided by the variety of ways risk can be conveyed. Currently there is a lack of evidence to support the most effective approach to use when communicating risk to different populations. Calman (1996) has identified three main issues that should be included in the content of risk communication, the certainty of the risk, the level of the risk and the effect of the risk on the individual or population. In order to be understood risk needs to be communicated in a meaningful context. Risk communications according to Edwards et al. (2002) should be kept simple and clear, relevant and responsive to the needs and values of the individual.

People have variable literacy and competency skills, which affects their ability to assimilate information. To inform effectively it is necessary to have an understanding of individual fears, ideas and expectations as well as an awareness of the differing interpretations of risk and the varied language of risk communication. Ineffective communication can lead to inappropriate decision making, confusion, complacency and unwarranted alarm (Berry, 2004).

2.6.2 Expressing Risk

Risk can be communicated in a variety of formats such as percentages, numbers, odds or probability, words and/or visual scales. Many people have difficulty understanding percentages and numbers. Therefore it is essential that health professionals are able to discuss risk in a variety of formats. Paling (2003) warns of the problems connected with the use of descriptive terms. They reflect the health workers perspective and the patients understanding may be different. Certain terms convey 'elastic concepts' including rare, unlikely, and probable (Glanz, 1996, cited in Edwards et al. 2002) implying they are open to numerous interpretations. Visual aids to show probabilities have been proven to be helpful when used to support explanations for individuals with poor literacy and numeracy skills.

2.6.3 Standardised Language

Calman (1996) discusses the need to clarify and standardise risk language to reduce miscommunications. This approach has been criticised as language is not static, it evolves with society, consequently implied meanings would alter over time (Edwards et al. 2002). The lack of flexibility to accommodate individual perspectives is also criticised (Walter and Britten, 2002). Berry et al. (2003) undertook a review of several studies that used standardised verbal descriptors. The descriptors used to explain risks associated with medication being: very common; common; uncommon; rare; and very rare (European Commission Pharmaceutical committee guidelines, 1998, cited by Berry et al. 2003). The results demonstrated individuals significantly over-estimated the risk of an adverse event occurring to themselves, but surprisingly, it actually lowered the likelihood of compliance. It could be interpreted from the results that participants treated the threat as fate or a game of chance. The study recommended a

cessation of the use of specific verbal descriptors until times of more supportive evidence.

Communicating risk is essential for health promotion and health gain with the aim being to bring about the intended positive effects. The process however is not straightforward and often fails to achieve the desired effect resulting in inappropriate decision making. Challenges include individual differences and cognitive and emotional limitations. Discovering if patients are aware of their risk of another stroke will indicate the efficacy of risk communication in current practice.

2.7 RISK PERCEPTION

Perceptions of risk are subjective, informed by experiences, values, emotions and the social environment, they are built up over time and consequently open to change. It is therefore difficult according to Ferner (2003) to establish what risks patients will actually take. Health professionals and patients interpret risk differently. Health professionals giving information base their perceptions mainly on scientific facts. The patients' perception however is more emotionally grounded, influenced by subjective elements and intuition rather than by objective scientific measures. Differences in perceptions are especially evident when medication is advised for prevention rather than for the treatment of symptoms (Jones, 2003).

The risk of having a stroke will be perceived differently by different people and this perception may change over time. A stroke could be perceived as a fatal threat, as fate or the consequence of a game of chance. What one person perceives to be a dreadful

outcome may be acceptable or a mild inconvenience to another. Berry (2004) claims there will never be a time when everyone agrees on a single level of acceptable risk.

Patients can underestimate and overestimate their risks and severity of illness. Either perception can potentially impact negatively on health behaviour. There is a tendency for individuals to overestimate the frequency of rare causes of death and underestimate the common causes (Conner and Norman, 2001). Van der Pligt (1998) claims over-estimations of risk are aided by personal experiences and media coverage, as over-estimations are more likely to occur if an event is easily pictured or recalled. Moreover, Beck and Frankel (1981, cited by Van der Pligt, 1998) found in a review of several studies that low expectations and underestimating susceptibility to risk provoked feelings of helplessness and decreased intentions to comply with preventative measures.

Perceived invulnerability, where individuals have a tendency to underestimate the extent to which they are personally vulnerable and overestimate the risks to others can be a defensive mechanism. It is a way of reducing fear and anxiety caused by the risk (Van der Pligt, 1998) and is labelled as 'unrealistic optimism' (Weinstein, 1980, cited by Conner and Norman, 2001, p.40). Other explanations for this behaviour include perceptions of control, egocentric bias, experience and beliefs, and self-esteem. Unrealistic optimism is more evident where individuals believe illnesses are preventable by individual action (Steenkiste et al. 2004). Van der Pligt (1998) suggests this is a major factor contributing to non-compliance with precautionary medical advice.

2.7.1 Changing Perceptions

Kreuter and Stretcher (1995) demonstrated that risk perception could be altered by the provision of individualised risk feedback. Patients at the start of the study who underestimated their risk of stroke were provided with information about their specific risks. Six months later their perception of risk was found to have increased. This study however only provides a 'snap shot' of altered risk perception at six months. It ignored the social and environmental determinants that impact on behaviour. A longtitudinal approach would identify if the intervention had been successful at sustaining this perception. Contrary to these findings, Weinstein and Klein (1995, cited by Van der Plight, 1998) claim it is extremely difficult to change individual's risk perception, and in their experience interventions often exacerbated the bias.

2.7.2 Perceived Stroke Risk

Limited research was identified within the literature that investigated patients perceived risk of a further stroke. Lloyd et al. (1999) studied very high risk patients ability to recall their increased risk. Even though the patients had all been informed of their risk and were on a waiting list for a surgical procedure to prevent a further stroke, very few could recall that they had an increased risk. Likewise Kreuter and Strecher (1995) concluded from their study of 1317 high risk patients that only 11% recognised their risk of stroke to be greater than average. Similar underestimated perceptions of risk were concluded in a study by Samsa et al. (1997). Their study population consisted of 1253 high risk patients, identified as patients who had either had a stroke or TIA or had other significant risk factors. However only 42% of patients in the study actually recognised their increased stroke risk. This was

especially true in the absence of stroke symptoms. They also found that patients who recognised their increased risk of stroke were more likely to comply with prevention strategies.

2.8 HEALTH PROMOTION AND RISK

Risk perception plays an essential role within health promotion, as the ability to judge individual risks is a vital element in decision making. Many models of health behaviour incorporate perceived risk as an important determinant of behaviour. Models include, the protection motivation theory, which relies on the appraisal of a health risk or threat to positively influence health behaviour and the health belief model that balances the perception of vulnerability to the risk and any drawbacks to benefits.

The above models assume people are able to identify and assess their risks and that decisions made about health and risk behaviour are based on conscious actions. The broad conceptual frameworks the models provide are useful. They highlight important issues to consider in relation to health behaviour including perceptions, value of health and self efficacy or as Whitehead, (2001) suggests they provide useful targets for persuasion.

Since the 1980's health promotion has changed its focus. There has been a move away from the lifestyle 'victim blaming' approach where individuals were considered totally responsible for their own health to an acknowledgement of governmental responsibilities, social, economic and environmental determinants that impact on

individual health choices. Behaviour change however remains the main approach within health promotion although it is not the main determinant of health (Naidoo and Wills, 2000).

2.8.1 Health Behaviour and Risk

To elicit a change in health behaviour Van der Plight (1998) suggests a perception of vulnerability to risk maybe a necessary requirement, but it is not sufficient to actually induce a change in behaviour. To be effective there has to be acknowledgement that behaviour can be as a consequence of the individual's environment. Consequently it is essential to consider other factors behind health related behaviour when planning health promoting strategies (Naidoo and Wills, 2000). Otherwise failure of behavioural change will be seen as the patient's fault and victim blaming will continue.

Secondary prevention interventions and the associated potential benefits should be available to everyone, as it is presumed individuals would wish to avoid further events or illness. It is also assumed by health professionals that they will also be willing to adapt their behaviour in return for health gain (Whitehead, 2001). However individuals do have the right to make their own choices. It is the health professionals responsibility to take the time and interest to ensure any decisions are fully informed and respect the person's choice.

Complying with medication is ultimately an individual decision, which entails associated responsibilities. A decision to comply is not made in isolation but affected by cultural, social and behavioural factors. An awareness and acceptance by health

professionals of the complex nature of compliance and the recognition that variable compliance rates are "normal" provides a more balanced and less moralistic view (Sawyer and Aroni, 2003).

Individuals differ greatly in the values they possess. Values affect the perceived degree of risk, which in turn influences health behaviour. Perceptions of risk and values can alter over time. Health professionals require an understanding of normal fluctuations in compliance behaviour as this has implications for health promotion strategies.

2.9 CONCLUSIONS DRAWN FROM THE LITERATURE REVIEW

This review of the literature has established confusion surrounding the term "compliance." Within the literature compliance and adherence are used interchangeably. However, health professionals and patients hold different views about its meaning. "Compliance" is now used to describe patient behaviour but in a less paternalistic way, which reflects the changing relationships between health professionals and patients. Patients are encouraged to actively participate in treatment plans, leading to agreement and informed decisions being made in relation to taking or not taking medication. Gaining an insight into why patients think they are taking aspirin and exploring their medication-taking behaviour will facilitate further understanding into patient behaviour and compliance.

Health promotion has seen a shift from blaming the individual about their ill health to refocusing on the reasons why people become ill. Risk factors are no longer addressed

in isolation but seen within a more holistic context. However, the identification and treatment of modifiable risk factors remains an important process. Exploration of patient awareness and their interpretation of risk factors will contribute to the processes and strategies of health education and promotion.

It is evident there are a plethora of factors that interact and impact on compliance with the interpretation of risk and risk communication being major determinants. It is understood that the provision of information is not enough to change health behaviour. Patient decisions are not based on scientific facts alone but also on intuition and emotional factors. To be effective, health messages need to be individualised, meaningful and useful to the individual. Having less paternalistic relationships with health professionals and increased participation in decision making will ensure patient decisions about medication are fully informed.

Whilst the literature gives some insight into compliance rates, there is less exploration of why patients comply or are non-compliant. This study is pertinent and timely within a health environment of finite resources, evidence based guidelines and population health improvement targets. An exploration of compliance behaviour with patients who have suffered a stroke is justified, as specific patient populations can have different experiences and issues related to the uniqueness of their disease. The study seeks to explore secondary medication behaviour and risk awareness in a group of patients at high risk of subsequent stroke.

Chapter 3

DESIGN AND METHODS

3.1 INTRODUCTION

The design and method chapter discusses the relationship between the study's research questions and the methods chosen to explore and answer those questions. The qualitative processes that were undertaken by the researcher in this exploratory and descriptive study are fully explained and critiqued. This includes the planning and rationale for the sample, the interview schedule design and construction, the collection of data and its organisation and analysis. There are advantages and limitations of the methods chosen and these are discussed. Ethical considerations were essential in this study. Details are given of the requirements and sensitivity required when interacting with the participants.

3.2 AIMS AND OBJECTIVES

The study aims to gain an understanding into compliance behaviour with aspirin when it is prescribed for secondary prevention of stroke. The study objectives were to describe the prior use of aspirin in patients who have previously had a stroke or TIA and have been admitted to hospital with a subsequent event. To explore if patients recalled being prescribed aspirin and to identify any potential factors that aided or inhibited compliance. A further objective was to examine if patients were aware of their personal risk factors for stroke and to understand their perception of risk of a further event. The final objective was to explore demographic factors (age, gender, social characteristics) that may possibly be associated with compliance behaviour.

3.2.1 The Research Questions

The following research questions were consequently formulated to guide the study.

- Do patients recall being prescribed aspirin for secondary prevention of stroke/TIA?
- How compliant are patients with their aspirin therapy?
- What factors facilitate compliance?
- What factors inhibit compliance?
- Are patients aware of their risk factors for stroke?
- At this exploratory level is there a relationship between compliance and other demographic factors? (age, gender, social characteristics)

3.3 THE POPULATION

It is estimated world wide there are 4.5 million deaths per year from stroke and over 9 million stroke survivors. Within the United Kingdom there are 110,000 first strokes and 30,000 recurrent strokes annually (Bath and Lees, 2000). Wolfe (2000) estimates the risk of recurrent stroke as 15-40% over the first five years, then an average risk annually of 4%. Hardie et al (2004) in a recent study estimates the risk for recurrent stroke to be six times greater than the risk of a first ever stroke in the general population, which is a similar finding to previous studies (Scmidt et al. 1988; Burn et al. 1994. Cited by Hardie et al. 2004).

Incidence rates however vary over time and by geographic area, (Engstad et al, 2003) depending on differing patterns of risk factors, age of the population and the stage of development of prevention strategies. Incident rates of TIA and minor strokes are

difficult to asses accurately, as many patients do not seek help due to the non-disabling or transitory nature of symptoms (Dennis et al. 1989). Within a population of 100,000 approximately 200 individuals with first stroke events and 60 with recurrent strokes would be expected to seek medical attention (Walker, 2000).

3.3.1 The Study Setting

The setting for the study was a 1,200 bedded, very large acute district general NHS Trust in the North West of England, serving a population of approximately 350,000. The Trust mainly serves two primary care trusts and admits approximately 1,000 stroke/TIA patients annually. Of these admissions approximately 25% are recurrent events (Trust, 2000). The Trust has a well-established stroke service, which was awarded NHS Beacon status in 2000-2002.

The details of all patients admitted to the Trust with a diagnosis of stroke or TIA are entered onto the Hospital Stroke Register. The register was established in 1997, it is maintained by the Stroke Co-ordinators and is embedded within the hospitals electronic patient information system. The register records current and retrospective data, including medical history and the level of physical and functional abilities of the patients.

3.3.2 Convenience Sample

The population for this study consisted of a convenience sample of 20 patients aged over 16 years admitted to the Trust with a diagnosis of recurrent stroke or TIA during a five-month period from January to May 2005.

Bryman (2001) describes a convenience sample as one that is selected because of its availability to the researcher. The approach used however has to be relevant for the focus of enquiry. A convenience sample was appropriate for this study, it enabled valuable data, insight and understanding into the phenomena under investigation. This method was also chosen due to considerations of time constraints and the availability and accessibility of the participants. The convenience sample consisted of 20 participants, which is approximately 8% of the recurrent stroke/TIA patients admitted annually to the Trust. The sample may not be representative of the population that has recurrent stroke or TIA's, therefore the findings are not generalisable.

Patients were recruited during their hospital stay rather than after discharge or from follow up clinics for the following reasons: Not all patients are reviewed in out patient clinics, therefore this group would only be a subgroup of the sample; this group of patients had already engaged in positive health behaviour demonstrated by clinic attendance, implying they may have been biased towards compliance. Patients on discharge would have been informed about many of the variables under study, therefore their recall of events prior to hospital admission may be biased.

3.4 INCLUSION AND EXCLUSION CRITERIA

The study's objective was to explore the patients' perspective and behaviour. It was therefore essential to collect the information directly from the patient.

3.4.1 Inclusion Criteria

Patients were eligible for the study if they fulfilled the following criteria: They were registered on the stroke register; They had evidence of a previous ischaemic stroke or TIA documented in the medical notes; They had been self medicating and consented to participate in the study.

3.4.2 Exclusion Criteria

Patients were excluded from the study if aspirin was contraindicated due to an allergy, a previous haemorrhagic stroke or TIA (Aspirin is contraindicated if a previous stroke was caused by a cerebral bleed). Patients were also excluded if they were taking other antiplatelet medication, anticoagulation therapy or if aspirin was contraindicated for any other reason. Stroke illness can affect patients in many ways with symptoms ranging from mild to very severe, the study was seeking personal views and experiences therefore this excluded patients who were unable to communicate effectively.

Patients were also excluded if they were not responsible for their own medication, for instance where other individuals are responsible for their drug dispensing and administration. This included patients with documented dementia and those admitted from nursing or residential homes. Finally patients who were either not able or refused to consent to the study were also excluded.

3. 5 METHODOLOGICAL UNDERPINNING OF THE STUDY

This study followed a phenomenological approach, which is based on the assumption that there is no single objective reality, but rather an accumulation of individual perceptions that can change over time. The study therefore enquired into how the participants construct their reality. Maykut and Morehouse (1994) explain this is achieved by examining the respondents' words or actions. Questions are asked through direct inquiry to reveal an insight and essence of their experience (Morse et al. 2001, Creswell, 2003).

3.6 SEMI-STRUCTURED INTERVIEWS

While it would be ideal to have an objective third party verification of compliance questioning patients according to Stephenson et al, (1993) is the most widely applicable method for investigating compliance. Semi-structured interviews provide a popular tool, as asking questions and recording answers promotes standardisation (Bryman, 2001). This approach was chosen for this study as it enabled appropriate data to be collected in a way that suited and did not embarrass the participants. For example, stroke illness may have compromised the ability to read, write or speak clearly and tape-recorded interviews could have been an issue for patients with slurred speech. Data interpretation could consequently have been difficult.

The interview schedule consisted of open-ended questions with some requiring specified responses, which could be grouped. This allowed collection of a range of factual and background data required for comparisons within the analysis.

The interview design also included some filter questions, which enabled other questions to be skipped. The design of question flow would have been complicated to follow if the questions had been delivered in another format. Face-to-face, non-threatening interviews also allowed the researcher to repeat any questions and responses to the patient ensuring the response intended was recorded.

Many studies have used quantitative research methods to investigate compliance. However given the inherent complexity of this study area the use of qualitative methods provided significant additional insight, especially into strategies respondents use to remember to take their medication. Quantitative questions alone might not yield the depth of response required to answer the research enquiry.

A major problem encountered when studying medication compliance is obtaining accurate information. The unreliability of self reports is noted by Kaplan and Simon (1990), who claim accurate responses are given by the non-compliant, but information from the compliant is often inaccurate and over-estimated. Responses are also limited by the participant's memory. Despite this Morisky et al. (1986) and Kaplan and Simon (1990), claim that asking simple and direct questions can yield very accurate information about adherence to drug regimes.

3.7 ALTERNATIVE RESEARCH METHODS

The research method has to be capable of answering the research enquiry. Consideration and sensitivity must be given to the study sample and the research setting. The accuracy of assessing compliance is complicated by many factors. This

study is enquiring about human experiences and behaviour. Alternative research designs and methods could have been used, but they would have produced different data. In ethnographic studies, data are collected using a variety of methods usually from in the field, including observation and interview (Bryman, 2001). This would have provided richer data but involved lengthy detailed interviews, which are not always practical within the acute hospital setting with ill or frail patients. A questionnaire constructed only of closed questions would have facilitated easier data processing however it may have induced forced choice answers. This might lead to frustration by the participant (Bryman, 2001) and would not reveal the participants' true experiences.

Observational studies do not rely on the interpretation of the respondent's words as behaviour is watched directly. An observational study was not feasible in this case. However if an observational study had been feasible it would have presented its own problems. For example Robson (2002) comments that being observed or even participating in a study could have an effect on the participants' usual behaviour.

Indirect observation methods using variables that are known to have a relationship with compliance could be instigated, for example, tablet counts or monitoring repeat prescriptions. However this would not guarantee participants were actually taking their medication and would fail to reveal insight into their reasons for non-compliance.

3.8 THE INTERVIEW DESIGN

The interview schedule (Appendix B) was designed to gain comprehensive coverage of the research objectives as explained by Nachmias and Nachmias (1981). The researcher visited a local stroke club affiliated to the Stroke Association to collect suggestions and opinions from the members about their experiences to assist with the development and phrasing of the interview schedule.

The interview schedule consisted of 37 questions. These were informed by the salient themes detected within the literature as possibly being influential with compliance. Additionally the schedule was complimented by adapted questions (numbers 31,33 and 35) taken from a self-reported study on compliance with antihypertensive medication by Morisky et al, (1986) used in an out-patient setting. The interview schedule was divided into three main areas, which covered socio-demographics, risk factors and perception, and understanding of aspirin therapy as secondary prevention. For respondent reliability, multiple fields were used to inform some of the questions.

3.8.1 Rationale for the Questions

The aim within the first section was to collect socio-demographic data including age, sex, occupation, whether living alone or co-habiting. These factors provided necessary data for profile and comparison. Confirming when a previous stroke or TIA occurred, estimated the time since commencement of aspirin. This allowed description of compliance behaviour over time and analysis between those who had suffered a previous stroke compared to those who had a previous TIA. The setting where the participants' previous stroke or TIA was managed was established as

perceptions may vary depending on past experiences. Also participants who had been admitted to hospital previously may have been commenced on aspirin prior to discharge. Differences may also have occurred in the level of information received, the understanding of risk factors and the perception of the threat of future illness.

3.8.2 Risk Perception

The second part of the schedule explored participants' knowledge of their risk factors for stroke. This was achieved by comparing the patients understanding of their risk factors to those documented in their health records. Ex-smoker was defined as having stopped smoking in the previous 6 months regardless of the numbers smoked per day. Alcohol intake was classified according to an average weekly consumption. A high intake was defined as 21 or more units for men and 14 or more units for women (DOH. 1995). High blood pressure was recorded if patients required anti-hypertensive medication.

Level of physical function and independence has been demonstrated as a factor that may affect compliance (Tamaroff et al., 1992). Therefore the Barthel Index (Mahoney and Barthel, 1965) score prior to admission was included. This is considered to be a reliable disability scale for stroke patients. It measures the ability of individuals to perform most of the activities of daily living and highlights functional problems. The maximal score is 20, which indicates full or near full functional independence. At most they would only require minimal assistance with their activities of daily living. The lowest score is 0 which represents a totally dependent patient (D'Olhaberriague et al.1996).

Communication and participation is recognised as an important process in the delivery of health care (Kreps, 2002). Patients were asked if their risk of a subsequent stroke had been discussed and to recall what was said. This provided insight into any communication between the patient and health care professional which may have affected the patients risk perception, although recall may be affected by time, memory and the new event.

3.8.3 Aspirin Compliance and Secondary Prevention

The final section of the schedule focused on secondary prevention, the participants level of compliance and their understanding about aspirin therapy. To measure compliance, a series of questions adapted from Morisky et al (1986) were asked that examined compliance behaviour from different perspectives including, asking how often they usually took aspirin, were they careless at times when taking aspirin, and did they stop taking aspirin when they felt better. Participants were also asked why they thought they forget to take aspirin and equally important what strategies they used to remember to take it.

Obtaining truthful responses about compliance is difficult. There is a tendency for respondents to give positive responses and questions are usually phrased so "yes" is the positive answer. Within the interview schedule the wording of two questions (31 and 35, adapted from Morisky et al 1986) has been reversed, therefore a "yes" response indicated a problem with compliance.

Health promotion advocates the importance of informed choice, therefore it is essential patients are aware of the rationale behind their prescribed medication.

Asking patients why they thought they were taking aspirin should illuminate their understanding and provide insight into any lack of awareness and/or misunderstandings.

3.9 LIMITATIONS OF THE STUDY

There is no gold standard for measuring compliance. There are disadvantages for using the particular method employed in this study as there are for all methods. These are presented below: -

3.9.1 Design

An interview schedule was designed for data collection as no previously used tool for this specific population was identified, therefore the tool was not validated or had reliability established. Reliability is also questioned as self reporting relies on patient honesty and memory. However, face to face interviewing can allow the participant and researcher to relax and develop a rapport which aids co-operation (Sapsford, 1999). Nevertheless Bryman (2001) warns of becoming too familiar, as this may bias the responses to subsequent questions. Qualitative data are also difficult to analyse and studies can be difficult to replicate or to apply to settings outside of the research area (Polit et al. 2001).

3.9.2 Participants

Responses can be affected by a desirability to give the "right" or "socially desirable" answer. The participant may not want to appear silly, wishing to be seen in a socially approved way (Sapsford, 1999) or want to avoid any confrontation, which can defeat

the purpose of the research. Robson (2002) comments, that data can also be limited by the participants' memory, motivation and personality which are all pertinent factors in this study.

3.9.3 Researcher

The researcher's personality and skills can also impact on the responses. The researcher is therefore required to be non-judgemental and non-threatening (Stephenson et al. 1993). A limitation of this study was that the researcher works within the stroke team as a Stroke Co-ordinator and had previously advised some participants on previous admissions.

3.9.4 Operational Issues

The management of stroke and TIA patients changed within the Trust during the course of the study. The introduction of new management guidelines led to less patients being hospitalised following a TIA or minor stroke as they were being treated as out-patients instead. Admitted patients were discharged quicker often within 48 hours, therefore insufficient time was available for the researcher to identify and approach some patients. These changes consequently impacted on the length of time taken to recruit patients.

3.10 ETHICAL REQUIREMENTS

This research study was approved by The School of Nursing, Midwifery and Social Care's Ethics Sub Committee of University College Chester (Appendix C) and Wirral Local Research Ethics Committee. (Appendix D) Permission was sought in

writing from all consultants working within the Medical Directorate and the Directorate of Medicine for the Elderly to include their patients in the study. (Appendix E) For awareness and politeness ward managers were also informed.

3.10.1 Patient Consent

All patients recruited into the study were given verbal and written information. (Appendix F) Consent was sought and research consent form signed (Appendix G) after ensuring patients' understood the nature and purpose of the study. Participation was entirely voluntary, no coercion was used. Reassurance was given that they could discontinue their involvement at any time without any untoward consequences and deciding not to participate would not affect their care.

3.10.2 Data Protection

Participants were informed their confidentiality would be assured, responses anonomysed, and the data would only be used for the purposes of this research project. Access to data would only be available to those involved with the study and the researcher's supervisors. The data would be kept secure and destroyed after completion of the project and any publications in keeping with the Data Protection Act 1998 and hospital policy.

3.10.3 Sensitive Questions

The avoidance of any unnecessary suffering was essential for the participants. This project aimed to enquire into the participants' medication behaviour which had the potential to cause embarrassment or upset. If the participant had not been compliant with aspirin therapy the interview may give rise to feelings of guilt. Therefore the

researcher was sensitive and allowed time on completion of the interview to answer questions either related or unrelated to the study and provided information as requested by the participants.

3.11 HOW THE STUDY WAS CONDUCTED

Recruitment occurred during five months from January to May 2005. Potential participants were initially identified from the stroke register. Twenty inpatients who met the inclusion and exclusion criteria were approached by the researcher and invited to participate in the study. Participation was voluntary and all agreed to take part. After the study had been discussed the patient information sheet had been read and any other questions answered, informed consent was obtained. The semi-structured interviews were conducted by the same researcher and took no longer than thirty minutes. The interviews were conducted in privacy in an informal, conversational, non-threatening manner allowing the participants to relax and talk freely. Patients were given the choice to have a carer or relative present, however all participants chose to be interviewed alone.

Lists of possible responses for questions that required specific answers were included on the researcher's interview schedule. This hastened the recording of responses but they were not declared to the patient, any other responses the participants gave were recorded verbatim. Following the interview, data were recorded from health records regarding risk factors and prescribed medication. The pre-admission Barthel Index score was obtained from the electronic stroke register.

3.11.1 Validity and Reliability

The validity of the tool was not assessed. However as valid responses are required the questions needed to be clear and unambiguous. They must also motivate the respondent to reveal truthful responses and measure what they purport to measure (Robson, 1993). Compliance behaviour therefore was assessed in a variety of ways by using a series of questions.

Reliability is the degree by which the results of the study can be replicated. This was enhanced by the same researcher asking all the participants the same questions in the same format. All the interviews were delivered in the same manner in a private area within the ward or at the bedside screened for privacy.

3.12 DATA ANALYSIS

The convenience sample provided qualitative data on a small group of participants. Therefore the objective of analysis was not to produce statistically significant results rather for the results to suggest possible relations for further study. The process of data analysis commenced during the phase of data gathering with the researcher making notes and reading data as it was obtained. The analysis was performed using content analysis as described by Bowling (2002) and Robson (2002). Descriptive and comparative statistical analysis was undertaken on the grouped data, where the data was sufficient enough to be grouped and Fishers Exact test for statistical significance applied. Analysis was aided by the statistical computer package, SPSS version 12 for Windows.

3.12.1 Content Analysis

Prior to the formal analysis all the data were read thoroughly several times to enable a feel for the dimensions of the responses (Denzin & Lincoln, 1993), and the research questions re-read to remind the researcher of the central issues. Each set of data was assigned a number. Responses to particular questions were brought together with their allocated data set number to allow for cross-referencing. The data were examined for common themes and phrases, which were examples of the same underlying concept. This process continued until no new themes emerged. Categories were then constructed and codes applied, Bowling (2002) warns to be careful as the data could potentially loose the richness of its qualitative nature during this process. For increased reliability, this exercise was repeated and agreed by an independent reviewer as differing insights can emerge from different individuals' analysis. If the reliability is low, Robson (2002) advises a repeat of the process and if necessary, revise the categories.

Exploring issues around compliance is sensitive and difficult. There are many instruments available to assess different aspects of compliance but there is no gold standard. A qualitative approach was chosen for this study as it met both the sensitive needs of the individuals in the study and the requirements of the research questions.

An aim of the research was not only to explore if participants were compliant but also to achieve an understanding and insight into issues around compliance from the participants' perspective which this method has facilitated. Due to local changes in the stroke /TIA management pathway, participants proved difficult to recruit. However, qualitative data from a convenience sample of 20 participants was collected.

Chapter 4

RESULTS

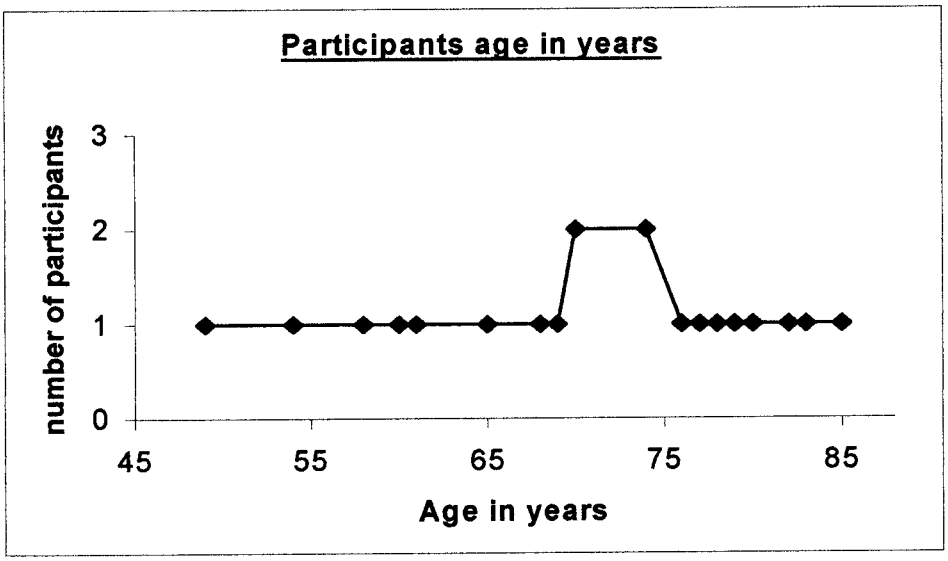
4.1 INTRODUCTION

The results from the data analysis are succinctly presented within this chapter. They describe the compliance behaviour of the convenience sample and suggest areas to focus on for future research.

4.2 SOCIAL AND DEMOGRAPHIC RESULTS

A total of 20 patients participated in the study, 10 were male. The median age was 72 years (range 49-85 years). (See chart 4.1)

Figure 4.1 The Age of the Participants in the Study



Excluding the reason for this admission 12 of the 20 participants had previously suffered a stroke and 8 a previous TIA. Within the sample, 2 participants had previously had multiple events of both stroke and TIA. The length of time since the participants had experienced their previous stroke ranged from 3 months to16 years, the median being 6 years. The length of time since the participants had experienced their previous TIA ranged from 4 months to 15 years. The median being less than 6 months. The median for both groups was 5 years. The length of time since the last stroke or TIA are displayed in table 4.1.

Table 4.1 Length of Time Since the Last Event

	Time since last event
<6months	7
6months -1 year	1
2 year	1
3-4 years	2
5-10 years	6
11-15 years	3

4.2.1 Social Information

11 of the 20 participants indicated they lived with someone and 9 lived alone. 19 of the participants had retired. All participants identified they were responsible for administering their medication, 17 obtained their own repeat prescriptions and one used a pharmacy delivery service.

4.2.2 Past Medical History

7 of the 20 participants had previously received care for their stroke or TIA from their GP and 13 of the 20 were admitted to hospital. 18 of the 20 participants had co-

existing medical conditions (See table 4.2) and were taking concomitant medication as well as aspirin. The number of concomitant medications including aspirin ranged from 3-10.

Table 4.2 Participants Co-existing Medical Diagnoses

Co-existing medical diagnoses	Frequency of diagnosis
Hypertension	11
Angina	5
Atrial Fibrillation	3
Arthritis	3
Asthma	2
Osteoporosis	2
Diabetes	2
Hypothyroidism	1
Past history of cancer	1
Peripheral vascular disease	1
Hypothyroidism	1
Irritable bowel syndrome	1
Macular degeneration	1
Kidney transplant	1

4.3 COMPLIANCE BEHAVIOUR

All of the participants recalled being prescribed aspirin following their previous TIA or stroke. 9 of the 20 participants were unaware of the dosage, and 10 out of 20 recalled they had received verbal and/or written information regarding aspirin.

When asked, how often do you usually take your aspirin? 15 out of 20 participants reported they usually took aspirin everyday, 3 revealed they took aspirin 4-5 times a week (Participants D, I. and K) and two females had discontinued taking it (Participants N and T). For reliability, 2 other questions enquired about compliance

behaviour. The questions were, are you careless at times about taking your aspirin? Out of the 18 participants who were taking aspirin, 5 said they were careless (Participants B, D, I K and Q). This included the 3 participants who had said they took aspirin 4-5 times a week, however the other 2 (participants B and Q) had said they usually took aspirin every day. In response to the question, when you feel better do you stop taking aspirin? 18 out of the 18 participants who were taking aspirin responded they would continue. However one participant who was asthmatic disclosed, when his breathing was difficult he did not take his aspirin for a few days.

The Barthel Index score is an indicator of independence, the maximum score possible is 20. 15 participants prior to this admission scored the maximum this included all the participants who had previously suffered a TIA. Scores ranged from 18-19 for 3 participants, which indicated a mild functional disability that would necessitate assistance with one or two activities of daily living. One participant scored 14, which indicates a moderate disability. The lowest Barthel index was 9, indicating the need for significant support at home.

The subgroups were too small to suggest any relationship between compliance and disability, length of time since the previous event and age or gender. When comparing participants with stroke and those with TIA, on how often aspirin was taken a Fishers Exact test indicated no significant difference with a P value of 0.216. (See table 4.3)

Table 4.3 Compliance Behaviour of Participants Who Took Aspirin

	How often do you usually take aspirin?		
	Every day	4-5 times a week	Total
Stroke	7	3	10
TIA	8	0	8
Total	15	3	18

4.4 FACTORS THAT AIDED COMPLIANCE

From the analysis three themes emerged as possibly aiding compliant behaviour. They were, routine, social support and having a "reason" to be compliant.

4.4.1 Daily Routine

14 of the 18 participants identified they took aspirin as part of a daily routine. 9 of the 14 responded that they took aspirin at breakfast time: -

> *"It's part of my breakfast... "* (Participant C)
>
> *" I take it everyday after a cup of tea before my breakfast."* (Participant R)
>
> *"I take it first thing before breakfast, It's automatic."* (Participant J)
>
> *"I lay them out the night before and take them before breakfast."* (Participant M)
>
> *"I take all my other tablets before breakfast, I put the aspirin in a cup to dissolve, I take it after breakfast."* (Participant Q)

3 of the 14 participants referred to taking their aspirin with their morning cup of tea or whilst waiting for the kettle to boil to make the first cup of tea of the morning: -

> *"I keep them by the kettle. I take it first thing when I go into the kitchen, while the kettle is boiling."* (Participant A)
>
> *"I take it first thing in the morning with a cup of tea and a biscuit."* (Participant O)

"When I come down in the morning I always put the kettle on. I dissolve the aspirin while waiting for it to boil." (Participant S)

2 of the 14 participants identified they took aspirin after their morning wash: -

"I take it first thing in the morning after having a wash." (Participant L)

" I keep them by the bed and take them after I've had a wash and breakfast. I always go back to the bedroom to take them, I'm a stickler." (Participant G)

4.4.2 Social Support

Social support for taking medication was demonstrated, as partners or relatives frequently checked that tablets had been taken: -

"My husband always asks me." (Participant L)

"The wife usually checks I've taken it." (Participant Q)

"I usually take it before I go to bed, the wife usually checks I've taken it." (Participant K)

"My sister checks when she comes." (Participant P)

Moreover one response illustrated a routine of taking medication together: -

"My husband always puts his and my tablets out at lunch time, we take them together." (Participant A)

4.4.3 Discovering a Reason

3 participants acknowledged their compliance behaviour had changed over time and identified a reason why this had improved. Reasons were "fear" and discovering a "purpose": -

"I didn't really use to bother but the GP told me off." (Participant Q)

"I used to miss taking it, but I don't anymore ... the last time my whole body down the right side went, it scared me. I take it everyday." (Participant S)

"I didn't use to bother, in the last six-eight months I've taken it every morning ... now I am retired I'm more aware of my health and I have to look after my grandchildren. " (Participant F)

4.5 FACTORS THAT INHIBITED COMPLIANCE

When asked, why do you think you forget to take your aspirin? Two themes were identified that inhibited compliance these were memory,

"I just forget." (Participants I ,K, D, Q)

and deliberate omission. A participant who had received a kidney transplant demonstrated this: -

" I run out, (of aspirin) I wait for my kidney prescription and get the drugs at the same time." (Participant B)

Deliberate omission was also demonstrated following forgetting. Participant I reported if she forgot to take her aspirin she would then *"... wait until the next day"* rather than take it upon remembering.

4.5.1 Discontinuation of Aspirin

Two categories were identified from the participants who had discontinued aspirin. These were feeling "well" and having to take other medication: -

"I took it for a about a year, I was fine, no problems, so I stopped taking it." (participant T)

" I take so many other tablets I decided to stop taking the aspirin." (Participant N)

Other responses from these 2 female participants are displayed in table 4.4.

Table 4.4 Participants who had Discontinued Aspirin

Respondent ID	**N**	**T**		**N**	**T**
Age	82	54	**Received information about aspirin**	no	no
Lives with	alone	partner	**Able to Identify some of their risk factors**	yes	yes
Time since previous stroke	6 years	5 years	**Current smoker**	yes	yes
GP care/ hospital admission	hospital	hospital	**High alcohol intake**	no	yes
Risk of another stroke discussed	yes	no	**Perception that they were at risk of another stroke**	no	no

4.6 RISK AWARENESS

4.6.1 Recall of Stroke Risk Being Discussed

6 of the 20 participants said the risk of a further stroke or TIA had been discussed after their previous event. Communication had been with the hospital doctor, GP, Stroke Co-ordinator or nurses. One participant could not remember who had given the advice but recalled the risk being discussed. Advice was paternalistic, threatening and scare tactics were employed:

"Stop smoking, or you could have another." (Participant O)

"You've have had one you could have another." (Participant B)

However in contrast one participant recalled the doctor giving no direction or advice as demonstrated by the following quote: -

"See how it goes." (Participant H)

No significant difference was detected between recall of strike risk being discussed comparing the stroke group and the TIA group. Fisher's Exact test gave a P value of 0.642. (See table 4.5)

Table 4.5 Recall of Risk of Stroke/TIA Discussed

Recall of risk being discussed			
	Yes	No	Total
Stroke	3	9	12
TIA	3	5	8
Total	6	14	20

4.6.2 Risk Perception of Another Stroke or TIA

When asked, did you think you were at risk of another stroke or TIA, 3 females and 3 males responded they thought they were, 12 participants thought they were not at risk and 2 did not know. The perceptions of the stroke and TIA participants were compared, the 2 participants who "did not know " were included in the "not at risk" category. The Fisher's Exact test gave a P value of 0.325. No significant difference was identified. (See table 4.6)

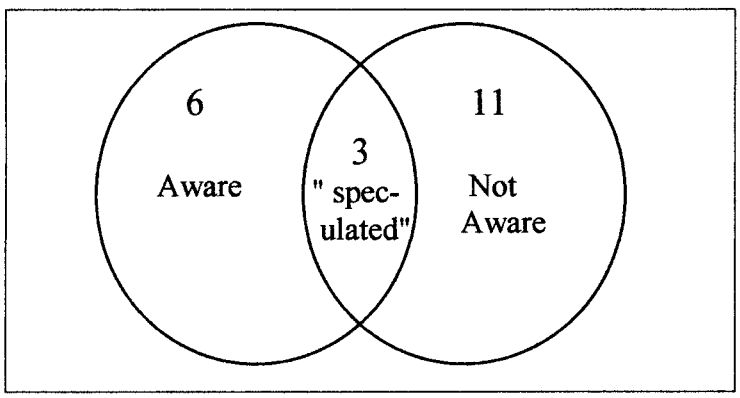
Table 4.6 Risk Perception of a Further Stroke/TIA

Perception of risk			
	Yes	No	Total
Stroke	5	7	12
TIA	1	7	8
Total	6	14	20

4.6.3 Awareness of Personal Risk Factors

Participants were asked, if they thought they had any risk factors for stroke. 6 of the 20 participants were aware they did, additionally 3 participants said they did not know however they continued to suggest possible risk factors and speculated some risks correctly. 11 of the 20 participants claimed they did not have any risk factors. The participants were then asked to state their risk factors. However out of those 9 participants who acknowledged they might have had risk factors no one identified all of their individual risks as documented in their health records. The participants' awareness of their personal risk factors is displayed in figure 4.2.

Figure 4.2 Participants' Awareness of Personal Risk factors



All participants had high cholesterol documented in their health record following their previous stroke or TIA which no one recognised as a risk factor. However all 5 current smokers identified their behaviour as a risk but continued to smoke and two participants recognised their previous stroke/TIA as a risk factor for another event. 3 of the 5 participants who smoked stated their risk of another stroke/TIA had not been discussed after their previous event.

The reported risk factors were compared to the risk factors documented in their health records. The results are displayed in table 4.7.

Table 4.7 Identified Risk Factors Compared to Documented Risk Factors

Documented risk factors	Frequency of risk factors In health care record	Frequency risk factor identified by patient	Frequency risk factor identified by patient expressed as a percentage
Current smoker	5	5	100%
Irregular heart beat	3	1	33%
High alcohol intake	4	1	25%
Hypertension	15	3	20%
Heart disease	5	1	20%
Ex smoker	8	1	12.5%
Previous stroke/TIA	20	2	10%
Raised cholesterol	20	0	0
Diabetes	1	0	0
Peripheral vascular disease	2	0	0

4.6.4 Unaware of Risk Factors

11 participants had responded they were unaware they had any risk factors for stroke. Out of this group 5 participants had their previous event over 5 years ago and the remainder less than one year ago. 7 of the11 participants had been admitted to hospital and 4 had visited their GP with their previous event. 8 of the 11 participants said the risk of stroke or TIA had not previously been discussed, half of these had been admitted to hospital. (See table 4.8)

Table 4.8 Recall of Risk of Another Event Being Discussed in Hospital or by GP

	Hospital managed	Managed by GP
Recall of Risks discussed	3	0
Recall of risks not discussed	4	4

4.7 REASONS WHY PATIENTS COMPLY WITH ASPIRIN THERAPY

When asked why do you take aspirin? Themes identified were: -

Following doctor's advice, fear of another stroke and due to the effects of aspirin.

Following Medical Advice - Out of the 18 participants who were taking aspirin 10 responded they did not know why they were taking it, and/or commented they took it because the doctor had told them to.

Fear- 3 out of 18 participants identified fear of another stroke as a reason for taking aspirin. One stated more positively he took it because he wanted to stay well.

Effects of aspirin - 6 out of 18 participants said they took aspirin because it "thins the blood" and one explained it was because of her blood pressure.

Chapter 5

DISCUSSION

5.1 INTRODUCTION

The rationale for undertaking this study was to explore issues related to compliance and to gain insight into patient awareness of their risk factors for stroke and TIA. Qualitative methods have allowed issues to be explored in greater depth than would have been possible with a quantitative approach. The methods used have enabled an insight into patients' perceptions and understanding. The findings have suggested that although compliance levels were good there are deficiencies in current practice. However, given the small sample size the results can be no more than exploratory and suggestive. It would require a survey of a much larger sample to produce statistically significant results. The study produced some interesting findings worthy of further consideration. These points will be discussed within this chapter.

There is scepticism about the validity of self-report, however to improve this the study enquired about compliance behaviour in multiple ways. The results are interpreted with caution as responses may have been affected by recall bias. Problems caused by the current stroke may also have affected memory, and perception of past events.

5.2 COMPLIANCE BEHAVIOUR

The study identified that all participants had been prescribed aspirin and good levels of compliance were practised. This could be attributed to the well-established stroke

service at the Trust which adheres to the RCP guidelines for secondary prevention of stroke (RCP. 2000,2004). However the study made no attempt to distinguish whether patients had been treated previously within the Trust or by the PCT's that it serves or by another provider. Previous studies revealed high levels of compliance up to 1year post stroke (Sappok et al. 2001; Hillen, et al. 1999). This study adds to these by suggesting good compliance with aspirin therapy beyond one year.

Taking aspirin was perceived by the majority of participants to be a very important activity. This was illustrated by the emphasis placed on insisting they never forgot and the development of strategies for remembering. Improved compliance through establishing a routine is reported by Kiortsis et al (2000). The routines evidenced within this study acted as "memory joggers" and most occurred during the morning. These included daily ritualistic activities such as mealtimes especially breakfast and washing. Social support and shared responsibility for remembering was also highlighted by some respondents, who expected partners to check the aspirin had been taken. No stigma caused by having to take medication indefinitely was detected as Elwyn et al (2003) reported can occur. This could be explained by the age group studied, as older people are more likely to have and maybe expect to have illness and disease in line with their peer group.

Interestingly, although taking aspirin was considered important and good levels of compliance were practised, the majority of participants lacked awareness of why they were taking it. Current health care practice encourages informed patients and active decision making. This study however illuminated that patients often do not know what their medication is for and the rationale for their compliant behaviour was

"because the doctor said to." This could possibly be attributed to a culture of trust and general acceptance to follow the doctor's advice without question of this age group. However societal values change over time therefore this finding may also change in the future.

5.2.1 Unintentionally or Intentionally Non-Compliant

The qualitative data provided an insight into "why" participants were non-compliant. Those that intentionally stopped taking aspirin were not irrational or deviant and they could explain the rationale behind their action. Although only two participants had discontinued aspirin further analysis of their responses revealed they both had a previous stroke around the same time 5/6 years ago, and Barthel Index scores of 20, indicated they made a very good recovery. Both perceived themselves not to be at risk of a subsequent stroke although one said the risks had been discussed. Both revealed unhealthy activities such as smoking, and one also reporting a high alcohol intake which suggests risk taking behaviour in line with Kyngas and Lahdenpera (1999) findings. However they both responded they had not received any information about aspirin. Having a facility to reaffirm health advice to these patients may have aided compliance. The discontinuation of aspirin therefore, maybe interpreted as unintentional non-compliance or as a medical error due to the health care team and system related factors.

5.2.2 Compliance Behaviour Over Time

The study demonstrates compliance behaviour can change over time. The qualitative data enabled specific incidents to be identified that positively and negatively altered perceptions and values. For example being scared or discovering a purpose motivated

participants to improve their compliance. Conversely over time participant T, had stopped taking aspirin because she felt fine and had no problems. Would compliance behaviour been different for this patient if periodical health advice had been offered? The Barthel Index score identified the majority of stroke participants as having only a minor residual disability, and due to the nature of TIA symptoms those participants were fully independent. The data therefore did not allow for comparison between those with lack of or differing degrees of symptoms. However, the majority who lacked residual symptoms maintained compliance. This may suggest that these participants value their previous good recovery and independence.

Age and accompanying memory decline are noted as factors that can inhibit compliance (Murray et al. 2004). Participants' memory was not assessed within this study and the convenience sample did not provided sufficient numbers of differing age ranges to discuss these relationships. The study however suggests that perceiving the drug to be important and establishing routine can facilitate compliance within the age group studied.

5.3 AWARENESS OF RISK AND RISK FACTORS

The study reiterated previous findings of Lloyd et al. (1999) and Kreuter and Strecher (1995) that patients at high risk of stroke are often unaware of their increased risk and their risk factors. Possible explanations for this could be memory, time related, denial of risk, information being given at the "wrong time," lack of understanding or "how" the risk was communicated. Effective risk communication is essential for informed decisions. However the study suggest that current practices of communicating risk

requires examination as many of the intended messages have either not been received as intended or not retained. If patients are to be involved in their care and perceive their risks accurately, it is imperative they receive and understand the information, as choices can be affected by how "risk" is delivered. However patients once fully informed have a right to make choices that may not be congruent with health care advice.

The risk factors for stroke can be divided into those currently applicable and those that have occurred in the past, consisting of ex-smoker and previous stroke/TIA. Interestingly the risk factors that were most frequently identified were the former. This maybe because there is nothing more "to be done" about the later group which may have occurred many years ago. Smoking and high blood pressure were the most frequently identified risks. The long-standing media coverage these two risk factors have received may also have helped with their recognition compared to cholesterol, which no one had identified as a risk factor. Cholesterol is a more recently identified and treated risk factor for secondary prevention of stroke. (Heart Protection Study Collaboration Group, 2004). Consequently some participants may not have been informed about their raised cholesterol level.

The study demonstrated knowledge is not always linked to health behaviour. All current smokers in the sample were aware smoking was a risk factor but had not altered their behaviour since their previous event. However three participants commented their risk of having another stroke had not been discussed. This could be explained as underestimating their susceptibility or "unrealistic optimism". Would their behaviour have changed if they had been informed of their individual risks?

Maybe it is not enough to report on risk factors generally and expect the individual to identify and "pull out " their applicable risks but to individualise the risk factors. Recall of the risk of stroke being discussed was low, again this finding could be affected by recall bias, denial, participants not wanting to disclose the truth and when in relation to their recovery they had been informed. However it presents challenges to health professionals.

The term "compliance" is value laden, within the NHS alternative terminology has been introduced including the terms adherence and concordance to promote a culture that encourages participation and informed patients. However this study supports that compliance is the most fitting term to describe patient behaviour in relation to taking medication. The findings suggest many participants comply because they are following the doctor's advice, without necessarily understanding why. Also, although the study provided minimal data on how the risk of another stroke was communicated, the responses were suggestive of paternalistic relationships. Patients are still expected to comply with recommendations made by health care professionals however they may not be fully informed.

Recent government modernisation initiatives promote a health service that is patient centred, personalised and responsive (DOH, 2000; DOH, 2003b). The above suggestive findings of paternalistic relationships and uninformed patients are issues to be considered in relation to patient choice. This is especially significant now with the advent of the new funding arrangements, payment by results. This will escalate competitiveness for patients within the NHS as patients will have increased choice where they are treated.

5.4 CONCLUSION

Despite the small number of participants and the study's exploratory nature it has produced some interesting findings, many affirming previous studies. For improved health outcomes and the effective use of resources, patients' medication behaviour is of great importance. However the decision to comply should be seen as a process by which patient values, understanding and perception of risk are congruent with the health advice received, with patients being active participants in their care.

The study answered most of the research questions. However due to small numbers the study was unable to suggest any relationship between compliance and socio-demographic factors. The main findings suggest that although compliance levels are good, there are deficiencies in current practice. The majority of participants were unaware of why they were prescribed aspirin although great emphasis was placed on the importance of not forgetting to take it. The participants were all at increased risk of stroke but awareness and identification of risk factors was low, especially the modifiable ones including high blood pressure and raised cholesterol. Strategies were identified that aid compliance and limited information was discovered about reasons that inhibited compliance.

Compliance is a very complex issue, affected by a plethora of factors that can make the problem seem daunting. However as there are so many factors involved there are many potential avenues for health promotion to explore. Medication compliance is only one factor within secondary prevention strategies for stroke. However, the exploration of medication behaviour in relation to taking aspirin has provided an

insight into the rationale for behaviour, which furthers current knowledge and has implications for health care workers.

5.5 RECOMMENDATIONS

As compliance is affected by a plethora of factors it is recommended that secondary prevention strategies should consider all patients as potentially non-compliant. It is therefore essential that secondary health promotion advice to support patients is tailored to take account of their individual values and beliefs.

A system is required that ensures individualised health information is revisited over time in order to reaffirm and check on patients understanding and perceptions and to review risk factors as new evidence emerges.

Incorporating medication into a daily routine, especially in the morning, can aid compliance, therefore patients should be encouraged to develop their own "memory joggers" to assist their memory and compliance.

It is recommended to include these findings in the development of a patient held diary for stroke and TIA patients. This would contain relevant individualised information about risk factors and medication. The diary would be expected to be produced at all future consultations with health care professionals therefore allowing for frequent discussions and updates.

5.5.1 Further Research

Areas for further research implicated by this study include: -

The communication of "risk" following a stroke, including exploration of "the appropriate time" for this to occur.

An evaluation of the effectiveness of the strategies used to support patient awareness and understanding.

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APPENDICES

NOTE REGARDING APPENDICES

This study was originally to be entitled *"The use of aspirin as secondary prevention of ischaemic stroke and transient ischaemic attacks: patient perspectives."* The title was altered to reflect the study more accurately. This change was prior to the submission of the D2 form but after ethical approval was granted. Therefore information in the appendices refers to the original title. Nothing else within the study has been altered. The School of Nursing, Midwifery and Social Care's Ethics Sub Committee at University College Chester and Wirral Local Research Ethics Committee have been notified of the change of title.

APPENDIX A

GLOSSARY

STROKE

"A syndrome of rapidly developing clinical signs focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin." (Hatona, 1976)

ISCHAEMIC STROKE

This is the most common type of stroke, it occurs when a blood clot blocks one of the arteries to the brain.

HAEMORRHAGIC STROKE

The cause of a haemorrhagic stroke is bleeding within or around the brain from a burst blood vessel.

TRANSIENT ISCHAEMIC ATTACK (TIA)

This is the same as a stroke except that all the symptoms have completely resolved within 24 hours.

ANTIPLATELET OR ANTITHROMBOTIC

These drugs inhibit clot formation in the venous side of the circulation Aspirin has an antiplatelet/ antithrombotic effect.

APPENDIX B

INTERVIEW SCHEDULE

(Red sections were not declared to participant)

1. Who was present at time of questionnaire completion?
   Researcher □ Patient □ Carer □ Other

2. Age

3. Occupation Retired □ Last occupation

4. Male □ Female □

5. Do you live alone?

6. Are you responsible for administering your own medication?

7. Who obtains your repeat prescriptions?

8. Have you had a previous stroke? (If no go to question11)

9. How many strokes have you had?

10. How long ago was your last stroke?

<6months □ 7 months-1year □ <2years □ 2-4years □ longer specify

11. Have you had a previous TIA?

12. How many TIA's have you had?

13. How long ago was your previous TIA?

< 6months □ 7 months-1year □ <2years □ <4years □ longer specify

14. Were you admitted to hospital with your last stroke/TIA?

15. Did you go to your GP with your last stroke/TIA?

16. Do you know if you have any risk factors for stroke?

17. Can you tell me what they are ?		Documented risk factors in health care notes
Ex smoker	☐	☐
Smoker	☐	☐
Heart Disease	☐	☐
Irregular heart beat	☐	☐
Diabetic	☐	☐
Raised cholesterol	☐	☐
Raised blood pressure	☐	☐
Peripheral vascular disease	☐	☐
High alcohol intake (above safe recommendation)	☐	☐
Previous stroke/ TIA	☐	☐

Any other risk factors the participant says

.....

18. Patients pre-admission Barthel score (Obtained from the stroke register) .....

19. Do you have any other medical problems?

20. What other medication do you take?

21. After your previous Stroke/TIA was your risk of another stroke discussed?

22. Who told you? Unable to remember ☐

23. What did they tell you? Unable to remember ☐

24. Did you believe you were at risk of another stroke or TIA?

25. Do you recall being prescribed aspirin following your stroke or TIA? (If answer no finish here)

26. Have you ever been given information about aspirin therapy?

27. Do you ever take the aspirin that was prescribed for you?

28. Do you have any difficulties taking aspirin?

29. Please explain what those difficulties are

(If the answer to question 27 was no)

30. Why don't you take aspirin?

(Finish here)

31. Are you careless at times about taking your aspirin?

32. What dose of aspirin do you take? Don't know □

33. Why do you think you forget to take your aspirin?

34. How do you remember to take your aspirin?

35. When you feel better do you sometimes stop taking aspirin?

36. How often do you usually take your aspirin?

Every day □ 4-5 times a week □ 1-3 times a week □ less than 1 a week □

Other .....

37. Why do you take aspirin?

APPENDIX C

Jo Southern

University College Chester

JS/RE/KS

UNIVERSITY COLLECE
CHESTER

- Dean -
School of Nursing, Midwifery
& Social Care DEL Marriss
BEd (Hons), MA, FCMI, RGN,
ONC, DN (Lond), RNT.

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Fax 01244 381090
Registered Charity 525938

leighton Hospital
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IQG *Tel 01925662017 Fax*
01925662487

Warrington Campus
Social Work
Crab Lane
Fearnhead
Warrington
WA2 aDB
Tel 01925530000
Fax 01925 530001

Dear Victoria

I am pleased to inform you that the Research Ethics Sub Committee of the School of Health and Social Care have approved your project 'The use of aspirin as secondary prevention of ischaemic stroke and transient ischaemic attacks: patient perspectives'.

Approval is subject to the following conditions.

1. That you provide a brief report for the sub-committee on the completion of your project.
2. That you inform the sub-committee of any substantive changes to the project.

May I take this opportunity to extend the best wishes of the Sub Committee and its Chairman for the successful completion of your project.

Yours sincerely

Jo Southern
Secretary to the Sub Committee

cc File

APPENDIX D

Wirral Local Research Ethics
Committee
Birkenhead
Operational Management
Arrowe Park Hospital
Upton, Wirral
Merseyside
CH49 5PE

Dear Mrs Little,

Full title of study: "The use of aspirin as secondary prevention of ischaemic stroke and transient ischaemic attacks: patient perspectives."
REC reference number: 04/Q1509/41
Protocol number: 1

The Research Ethics Committee reviewed the above application at the meeting held on 15 September 2004.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion to the above research on the basis described in the application form, protocol and supporting documentation.

The favourable opinion applies to the following research site:

Site: Wirral Hospital NHS Trust
Principal Investigator: Mrs Vicky Little

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

Document Type: Application
Version:
Dated: 25/08/2004
Date Received: 27/08/2004

Document Type: Investigator CV
Version:
Dated: 27/08/2004
Date Received: 27/08/2004

Document Type: Investigator CV
Version:
Dated: 27/08/2004
Date Received: 27/08/2004

Document Type: Protocol
Version: 1
Dated: 30/07/2004
Date Received: 27/08/2004

Document Type: Covering Letter
Version:
Dated: 12/08/2004
Date Received: 27/08/2004

Document Type: Summary/Synopsis
Version:
Dated: 27/08/2004
Date Received: 31/08/2004

Document Type: Interview Schedules/Topic Guides
Version: 1
Dated: 30/07/2004
Date Received: 27/08/2004

Document Type: GP/Consultant Information Sheets
Version: 1
Dated: 30/07/2004
Date Received: 27/08/2004

Document Type: Participant Information Sheet
Version: 1
Dated: 30/07/2004
Date Received: 27/08/2004

Document Type: Participant Consent Form
Version:
Dated: 27/08/2004
Date Received: 27/08/2004

Document Type: Other
Version:
Dated: 13/07/2004
Date Received: 27/08/2004

Management approval

The study may not commence until final management approval has been confirmed by the organisation hosting the research.

All researchers and research collaborators who will be participating in the research must obtain management approval from the relevant host organisation before commencing any research procedures. Where a substantive contract is not held with the host organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Notification of other bodies

We shall notify the research sponsor, Wirral Hospital NHS Trust and the Medicines and Health-Care Products Regulatory Agency that the study has a favourable ethical opinion.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

REC reference number: 04/Q1509/41 **Please quote this number on all correspondence**

Yours sincerely,

Mrs Julie Garner
Chairman

Enclosures *List of names and professions of members who were present at the meeting and those who submitted written comments*

Standard approval conditions

APPENDIX E

CONSULTANT LETTER

July 2004

Dear Dr

I am studying for a MSc in Health Promotion and Health Education at University College Chester. My dissertation research project is entitled ***"The use of aspirin as secondary prevention of ischaemic stroke and transient ischaemic attacks: patient perspectives."*** This project has been approved by both The School of Nursing, Midwifery and Social Care's Ethics Sub Committee in University College Chester and the Wirral Local Research Ethics Committee. My supervisors are Dr. Melanie Maxwell at Arrowe Park Hospital and Dr. Elaine Hogard from University College Chester. The study is planned to start September 2004.

I would like permission to approach suitable patients under your care who have been admitted to the hospital with a recurrent stroke or TIA, to participate in the study. Their involvement would be entirely voluntary and consist of an interview with myself about their use of aspirin. This would take place on the ward and would not disrupt any usual care or treatment. I would also need to access the medical notes to confirm diagnosis and risk factors.

The care and management patients receive will not change regardless of their decision to participate or not. They can also change their mind and withdraw from the study at anytime. The findings of the study will be disseminated through stroke meetings and publications sought in health journals. If you would like any further information please do not hesitate to contact me. If you would rather your patients were not involved in this study please inform me by August 30th 2004.

Thank you.

Vicki Little
Stroke Co-ordinator

APPENDIX F

PATIENT INFORMATION

May 2004

Patient Information Sheet

"The use of aspirin as secondary prevention of ischaemic stroke and transient ischaemic attacks: patient perspectives."

Invitation
You are being invited to take part in a research study. Before you decide it is important to understand why the research is being done and what it will involve. Please take time to read the following information and discuss it with others if you wish. Ask me if there is anything you do not understand or if you would like any further information.

1. Why is this study being done?
This research study will form part of my work towards a Masters degree at University College Chester in Health Promotion and Health Education.

2. What is the purpose of this study?
The purpose of this study is to find out about the use of aspirin in patients who are admitted into hospital with a stroke or Transient Ischaemic Attack (TIA or mini stroke) and have suffered a stroke or TIA in the past. The aims are to find out, if patients take aspirin what makes them take it, or if there are any problems, reasons or experiences patients have which have made them choose not to take it. Your responses will help to discover if changes need to be made to current secondary prevention stroke management.

3. Do I have to take part?
It is up to you to decide if you would like to take part in this study, it is entirely voluntary. If you decide to take part you are free to withdraw at any time without giving a reason. If you decide to participate or not to be involved with this study all your usual care and treatment will continue.

4. What will happen if I take part in the study?
If you agree to participate, it will involve answering a series of questions about aspirin use and your risk factors for stroke. It will last no longer than 30 minutes This will be carried out at a planned time with yourself. If you would like a relative can be present. The interview will either take place at the bedside or in a quiet area on the ward. This interview will not stop any treatments or therapy. I will also need to access your medical notes to confirm your diagnosis and risk factors. If the interview cause any questions or emotional feelings to surface, time will be given to fully discuss any concerns.

5. What will happen to the information I give you?
For confidentiality your responses will be made anonymous. Access to your answers will only be made available to those directly involved with this study. The information may be used for publications in nursing or medical journals and for presentations. The information will be destroyed after completion of the project and any publications in keeping with the Data Protection Act 1988 and hospital policy.

6. **Does my consultant know about this study?**
Your consultant is aware of this study and has given permission for his/her patients to participate. The study has been approved by The School of Nursing, Midwifery and Social Care's Ethics Sub Committee in University College Chester and by the Wirral Local Research Ethics Committee.

7. Contact details
Vicki Little

Arrowe Park Hospital
Arrowe Park Road
Wirral CH 49 5PE

Monday- Friday 09.00 -17.00 Internal phone extension 2279, Bleep 7009
Direct line 0151 604 7397
Weekends or after 17.00 - 01244 851641

If you or your relatives have any questions or would like to talk to me further please do not hesitate to contact me directly or ask your nurse to contact me from the details above. Thank you for taking the time to read this letter.

APPENDIX G

Wirral Hospital NHS
NHS Trust

RESEARCH CONSENT FORM